CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

REMARKS

Claims 1-43, 45-63, 65-70, 72, 74 and 76-81 have been subjected to a 74-way restriction. In response Applicants provisionally make an election and traverse the restriction for several reasons described below.

Election

Applicants provisionally elect GROUP 1, comprising administering a bile acid.

Traversal of the Restriction Requirement

A. Claims Directed to the Pharmaceutical Formulation and Method of Treating Should not be Restricted

The Examiner has improperly restricted the claims encompassed by method claim 1 from those encompassed by the pharmaceutical formulations of independent claim 78. Thus, Groups 1-26 and 67-74 should all be examined together because Examiner has improperly substituted MPEP Chapter 800 practice for the PCT Unity of Invention Standard. See Office Action, p. 13.

1. Applicable Law

According to the Administrative Instructions of PCT, Unity of Invention as set forth in Rule 13.2 expressly states that a product and a method for using the product may be examined together. For example,

> (e) **Combinations of Different Categories of Claims.** The method for determining unity of invention under Rule 13.2 ***shall be construed*** as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
>
> > (i) in addition to an ***independent claim for a given product***, an independent claim for a process specially adapted for the manufacture of the said product, and ***an independent claim for a use of the said product***, or .... (Emphases added).

Paragraph (e) states, that the combinations of different categories of claims must be interpreted to permit examination of claims directed to products and method of using the product. The language "shall be" is not discretionary but required.

Thus, Groups 1-26 and 67-74 must be examined together absent some other evidence as to why they should not.

2. Prior Art

Examiner has applied the Daniel [sic] reference (which is actually Matsumori, et al.). Matsumori performs experiments in mice using ouabain, a glycoside. Matsumori is completely irrelevant and cannot reasonably be found to render the claims obvious.

The compound that Matsumori uses, ouabain, is not encompassed by any of the claimed methods, including the elected compound a bile acid. Ouabain is a glycoside.

Matsumori has no data on treating congestive heart failure. Neither does he disclose any method for doing so. All of Matsumori's experiments take place within 4-6 hours. Chronic heart failure progresses over years. Thus, Matsumori's figure 1 [cited by examiner] showing that ouabain provided an increase in cytokines after 4-6 hours is completely irrelevant as to whether the symptoms of heart failure have been addressed.

Examiner states that Matsumori shows that ouabain diminishes the adverse effects of endotoxin. LPS killed 95% of animals within 48 hours postinjection. All that Matsumori shows is that ouabain inhibited the LPS-induced levels of three cytokines, and somewhat reduced this mortality.

There is no basis to conclude any effect on the heart, failing or healthy, has been shown. Ouabain binds to Na-K ATPase, a plasma membrane enzyme that *all* cells possess.

Accordingly, Matsumori does not render Applicants' claims obvious and cannot support Examiner's finding of lack of unity of invention.

B. The Form of the Restriction Requirement is not Proper

The issued restriction requirement should have been an election of species.

This is supported by the fact that Examiner states that if any one of Groups 1-26 is elected, claim 1 will be examined together with Groups 1-26. This means that Examiner correctly concludes that Groups 1-26 encompass species or embodiments of the generic method defined by claim 1. Thus, what Examiner seemed to intend was an election of species of the main method of claim 1.

To the extent that the compound in claim 1 may be a bile acid, it is respectfully suggested that the above election is actually an election of species that

also satisfies the issued restriction. Thus, main claim 1 and its dependent claims should be examined with respect to the compound being a bile acid.

Conclusion

According to the PCT's administrative instructions, there should be restriction between the formulation and method claims. Further, the foregoing discussion indicated why Matsumori cannot render the claims unpatentable, thus, unity of invention indeed exists.

Groups 1-26 and Groups 67-74 should therefore be examined together under PCT rules. Examiner has been respectfully reminded that PTO restriction practice pursuant to MPEP § 800 does not apply in this case.

Respectfully Submitted,

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